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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/759,345	ROBINSON, DOUGLAS H.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-14,19-23,30 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-14,19-23,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 2-10-2006 are acknowledged. Claims 4, 6, 8-11, 13-14 and 19-20 have been amended. Claims 1-3, 15-18 and 24-29 have been canceled. Claims 30 and 31 have been added. Claims 4-14, 19-23 and 30-31 are pending and currently under examination.

Claim Objections Withdrawn

The objection to claims 26 and 28 for the mixing of singular and plural terms is withdrawn. Cancellation of said claims has rendered the objection moot.

Claim Rejections Withdrawn

The rejection of claims 1-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,022,730 is withdrawn in light of the Terminal Disclaimer filed on 2-10-2006.

The rejection of claims 24-29 under 35 U.S.C. 112, first paragraph, as failing to comply with the biological deposit requirements is withdrawn. Cancellation of the aforementioned claims has rendered the rejection moot.

The new matter rejection of claims 24-29 under 35 U.S.C. 112, first paragraph, based on the limitation that the claimed cell is not a transgenic cell is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claims 1 and 15 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the language "under low oxygen conditions..." is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claims 2, 3, and 15 under 35 U.S.C. 112, second paragraph, as being vague and indefinite and confusing by the use of the phrase "subjecting the cells to an aerobic culturing step" is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claims 24 and 25 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "derived" is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claims 24 and 25 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "evolved" is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claims 24 and 25 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "pleiomorphic cell" is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claims 27 under 35 U.S.C. 112, second paragraph, as being 29 are rendered vague and indefinite by the use of the phrase "morphology that is neither prokaryotic nor eukaryotic" is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention is withdrawn in lieu of the rejection set forth below.

Claim Rejections Maintained

35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4-14, 19-23 and 30-31 are rejected under 35 U.S.C. 101 for the reasons set forth in the previous Office action in the rejection of claims 1-29. The claimed invention is not supported by either a credible asserted utility or a well established utility, as the **disclosed invention is inoperative**.

The claims are drawn to a method for **producing a bacterium** that contains a eukaryotic and/or viral gene, which comprises culturing virally infected eukaryotic cells under low oxygen conditions to produce a bacterium containing a eukaryotic and/or viral gene. The specification at page 9 indicates that the present invention provides a process for producing a bacteria containing at least one eukaryotic gene. The specification at page 9 further states "the process of the present invention, sometimes called *de novo* speciation, can be divided into the following stages:

(I) Culturing virally-infected eukaryotic cells under low oxygen conditions to **produce a bacterium** containing a eukaryotic and/or viral gene; and

(II) Selecting and replicating at least one such bacterium."

Accordingly, the claims and the specification call for a method for producing a bacterium containing a eukaryotic and/or viral gene, which comprises culturing virally-infected eukaryotic cells under low oxygen conditions to produce a bacterium containing a eukaryotic and/or viral gene whereby neither the bacterium nor the bacterial genome is introduced. Barron's Law Dictionary 3rd Edition defines *"de novo "* as "new, young, fresh; renewed, revived..." and Webster's II New Riverside Dictionary defines "speciation" as "the evolutionary process by which new species are formed." Therefore, Applicant is calling for the *de novo* "creation" of a

new species and/or the "creation of a life form", i.e., the bacterium, from eukaryotes without the introduction of bacterial genes or the bacteria themselves. However, current knowledge of scientific principles maintains that prokaryotes and eukaryotes constitute separate and distinct life forms having many differences in structure and function. The most striking difference pertains to the presence or absence of a nucleus. That the only recognized process in the art for the acquisition of new traits is mutation is well settled. Moreover, the process of the acquisition of new traits is a slow process that requires so many changes that more than anaerobic cultivation for a few hours or even a few years is necessary. To the best of scientific knowledge, the evolution of first one-celled and then many-celled eukaryotes from one-celled prokaryotes is believed to have taken several million years and not a few hours or days. Likewise, it appears that Applicant is calling for the "spontaneous" production of a new bacterium without the introduction of the bacteria or the bacterial genome. It should be remembered that Louis Pasteur effectively disproved the principles of spontaneous generation at the end of the last century in historical experiments. Therefore, the specification fails to show a clear correlation between culturing retrovirally infected animal cells in the amount of oxygen given and the "creation" (i.e., the production) of a new species of bacteria.

Applicant argues:

1. The Board acknowledged that the record supported Applicant's arguments that the claimed process, when practiced under sterile conditions, starts with cells belonging to one species (a eukaryotic cell) and "resulted in the 'production' of cells that are identifiable as belonging to another (a bacterium) i.e. *de novo* speciation.

2. The Examiner has not framed his rejection in terms of a lack in the claims of a limitation requiring that sterile conditions be maintained throughout the process.

3. The Board was "unable to identify any evidence upon which the Examiner relies upon to support [the Examiner's] assertion" thus indicating that the Board agrees with Applicant with regard to the operability of the claimed invention.

4. The amendments, based on the Board's comments are sufficient to overcome the rejection.

Examiner Rebuts:

With regard to Point 1, the cited portion of the remand brief is merely a summary of Applicant's arguments and the Declaration of Dr. Steuer. This summary cannot be construed as the Board agreeing with said arguments. In point of fact, the Board clearly states that Applicant's arguments are directed to inventions other than that being claimed (see page 7 of the Board's Brief).

With regard to Point 2, contrary to Applicant's assertion, said deficiency in claim language was addressed in the rejection (see page 6 of the last Office Action).

With regard to Points 3 and 4, the cited comment by the Board was with regard to the properties of the "recovered bacteria". Contrary to Applicant's assertion, this cannot be construed as the Board agreeing that the claimed method is operative. In point of fact, the Board declined to make a decision regarding the operativeness of the claimed method (see page 9-10 of the Board's brief). Moreover, the amendments to the instant claims are insufficient to overcome this rejection. Applicant is reminded that the basis of the rejection is that the claimed method as disclosed is **inoperative.** As Applicant has failed to demonstrate that the execution of the claimed method steps would result in the **production of a bacterium containing a eukaryotic and/or viral gene,** the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-14, 19-23 and 30-31 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the previous Office action in the rejection of claims 1-29. The specification, while being enabling for a method for isolating a bacterium comprising aseptically culturing retrovirally transformed human capillary microvascular endothelial cells (ATCC CRL 11655); subjecting said culture to an anaerobic culturing phase wherein said culture is exposed to oxygen conditions corresponding to an atmosphere containing of about 0 to 2% v/v oxygen for a period of between 18 and 24 hours; exposing said culture to oxygen conditions corresponding to an atmosphere containing greater than 2% v/v oxygen; subjecting said culture to an additional anaerobic culturing phase wherein said culture is exposed to oxygen conditions corresponding to an atmosphere containing of about 0 to 2% v/v oxygen for a period of between 18 and 24 hours; subjecting said culture to an additional aerobic culturing phase under aseptic culturing conditions and corresponding to an atmosphere containing greater than about 2% v/v oxygen; isolating a bacterium from the culture (either *Staphylococcus aureus* ATCC 55589, *Staphylococcus capitis* ATCC 55590, *Staphylococcus hemolyticus* ATCC 55592, *Staphylococcus epidermidis* ATTC 55591 or *Micrococcus luteus* ATCC 55588), does not reasonably provide enablement for methods for **producing** a bacterium that contains a eukaryotic and/or viral gene comprising culturing virally-infected eukaryotic cells under low oxygen conditions. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

Applicant argues:

1. The amended claims no longer recite the terms "production" or "producing" thus obviating the rejection.

2. The Board has accepted the term "production" as appropriate for describing the invention and that its use does not refer to spontaneous generation or creation of life (see pages 7-8 of remand.

3. The rejection based on the lack of enablement of the production of a new line, as opposed to the isolation of such a line has been specifically found to be without merit by the Board.

4. The Steuer Declaration, the Robinson Declaration, and the Final Report attached to the Robinson Declaration, establishes within a reasonable degree of scientific certainty that the claimed methods are enabled.

5. Dr. Steuer states in his Declaration that he does not agree with the reasoning and conclusion presented in the Office action; that aseptic cell culturing techniques were employed; and that it is his opinion that any scientific inquiry wherein one must "rule out" contamination is meaningless.

6. The Examiner has not provided any evidence that impeaches or rebuts Dr. Steuer's Declaration.

7. The fact pattern of *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.* exists in the instant case: the characterization and identification of the cell produced thereby are all within the ordinary skill in the art.

8. The experiments not resulting in a new cell type were not done in accordance with the claimed methods and hence do not prove unpredictability of the claimed method.

9. Uncontroverted evidence of record shows that every experiment carried out in accordance with the claimed methods produced a new cell type as recited in the claims.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, while the terms "production" and "producing" have been eliminated from the claims, the claimed method steps are still drawn to a method of producing a bacteria by culturing eukaryotic cells under specified conditions. Moreover, the specification consistently refers to said methods steps as being a method of "producing a bacteria" (see pages 1, 5, 7, 9, 10 etc... for example).

With regard to Point 2, the Board's use of the term "production" cannot be construed as a tacit acceptance of Applicant's arguments. The Board was merely utilizing the terms and phrases set forth in Applicant's brief and the Examiner's answer. Nowhere in the Board's Remand Brief does the Board set forth what they construe to be encompassed by the term "production".

With regard to Point 3, contrary to Applicant's assertion, the Board made no finding with regard to instant rejection. The Board states very clearly on page 6 of their Remand Brief that they take no action on the merits of the appeal.

With regard to Point 4, contrary to Applicant's assertion, the Steuer Declaration and the Final Report do not establish within a reasonable degree of scientific certainty that the claimed methods are enabled as neither demonstrate execution of the claimed methods steps would lead to

the production of a bacteria containing a eukaryotic and /or viral gene. It should be noted that this point was made by the Board on page 8 of their Remand Brief.

With regards to Points 5 and 6, contrary to Dr. Steuer's assertion, contamination is usually the first "explanation" to be ruled out when confronted with data that flies in the face of accepted scientific theory. Since the art does not support the belief that one can produce a bacteria by culturing virally infected eukaryotic cells, the skilled artisan would necessarily assume that contamination could be the cause and would move to "rule out" this possible explanation. Moreover, the skilled artisan would readily acknowledge that contamination is always a possibility no matter how closely aseptic procedures were followed. Moreover, it should be noted that none of the Declarations of record were made by disinterested third parties. Finally, *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention **is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art."** "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, **if little is known in the prior art about the nature of the invention** and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. **Thus, Applicant assumes a certain burden in establishing that inventions involving physiological activity are enabled**.

With regard to Point 7, *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co* is not germane as the instant case is drawn to a method of producing a bacterium from a eukaryotic cell and said method is not known in the art.

With regard to Points 8 and 9, contrary to Applicant's assertion, all the experiments carried out in accordance with the claimed method **did not** produce a new cell type as recited in the instant claims. For example the e "bacteria" disclosed in the Steuer declaration and Final report were not shown to contain a eukaryotic and/or viral gene.

As outlined previously, it does not appear that the claimed method would be suitable for the production of bacteria from any and **all virally infected eukaryotic cells**. From the record of the written disclosure specific bacteria were obtained by the cultivation of the specific cell lines in specific media. In view of the specific nutritional requirements of different types of "cell cultures" and of different bacteria, there is no reasonable expectation that any and all types of bacteria may be "produced" or even isolated from any and all cell cultures by the procedure claimed. For example, any anaerobic bacteria would be destroyed upon exposure to aerobic conditions. In addition, the claims lack specific method steps for the recovery of the bacteria. Thus, it is unclear that the claimed method would be suitable for the recovery of any and all bacteria, a few of which may be present, but not detectable by certain means. Moreover, one of ordinary skill in the art would not reasonably expect any and all possible viral infected eukaryotic cell cultures to harbor or to be contaminated by bacteria, especially if stringent aseptic technique is used. In this respect, it is apparent that only very specific sources of cell cultures would be suitable for the claimed invention. However, the specification provides insufficient guidance for one skilled in the art to obtain such cell cultures. In addition, it is unclear what precautions were taken in the instant case to

assure that the bacteria harvested are not incidental contaminants inadvertently introduced into the cell culture. Moreover, it is well known in the art that bacteria are common cell culture contaminants (see Freshney "Culture of Animal Cells: A Manual of Basic Technique 2nd Edition", Alan R. Liss, Inc., New York, 1984, pages 207-208). Thus, there is no clear correlation between the instant method of culturing and the production of **new strains of bacteria**.

It is also apparent that the claimed method is unpredictable and would appear to depend on the type of cell cultured and the type of virus employed. It is unclear how the cell culture is chosen to have a reasonable a degree of certainty that bacteria as required can be "produced", in the absence of positive steps to modify existing bacteria and to assure the survival of the cell culture for a time period. What step actually produces the bacterium? Is it sufficient for any bacterium to be grown in any virally infected eukaryotic cell in order to acquire both eukaryotic and viral genes? Accordingly, in view of the lack of guidance, the claims as written constitute nothing more than an invitation to experiment.

The present invention would also require undue experimentation to practice in view of the unpredictable completion of the culturing steps. The specification indicates that the cultured cells under anaerobic conditions results in the death of the eukaryotic cells. However, the claims include no such limitation, accordingly, it is unclear if the eukaryotic cells are to be living or dead at this point. Likewise, the specification indicates that culturing under low oxygen conditions results in the production of the bacterium. However, what actual step leads to the production of the bacterium? Where are the genetic elements necessary for this event to occur (i.e., what is the origin of the bacteria)? While it is true that bacteria are a frequent contaminant of a cell culture, it is not apparent that the purpose of the present invention is to recover

contaminants. Furthermore, how long is one of skill in the art to culture the virally infected eukaryotic cells. On the other hand, how long does one of skill in the art have to culture the cells anaerobically in order to "produce" a bacterium containing a eukaryotic and/or viral gene? Likewise, which eukaryotic cells should one use, and what virus should be employed?

Additionally, it is unclear how one of skill in the art would determine and assure that the actual viral and/or eukaryotic genes are indeed intact genes picked up rather than random fragments thereof. The cell line of the specification uses retrovirally-infected cells. However, by convention, retroviral genes have been found to be ubiquitous in all types of different organisms, such that virtually any cell culture would reasonably be expected to have at least pieces of DNA from these viruses. In addition, it is well known in the art that many animal species harbor endogenous retroviral genes. However, it is unclear how one skilled in the art would determine that the cell culture has these "genes" without undue experimentation. Regarding the genes or fragments that are to be present in the bacteria, it is unclear whether such pieces are to be stably incorporated into the genome and that proteins will be expressed by them. For DNA to integrate, homologous recombination is needed, such that the respective sequences must already be present in the bacteria. Therefore, it is unclear whether a stable product is produced.

In view of the lack of guidance provided by the disclosure, the limited number of working examples, the state of the art, the breadth of the claims, and the unpredictably nature of the invention, it would take an undue amount of experimentation to practice the claimed invention.

Moreover, contrary to Applicant's assertion the specification is not enabled for methods for **making, producing or generating** a bacterium that contains a eukaryotic and/or viral gene. As stated previously, the specification is only enabled for a method for **isolating** a bacterium comprising aseptically culturing retrovirally transformed human capillary microvascular endothelial cells (ATCC CRL 11655). The specification does not

provide any mode of making and using the claimed invention throughout the scope of the claims. Contrary to the Applicant's assertion, the Declarations by Drs. Robinson (i.e. the Final Report) and Steuer do not establish that the methods disclosed in the instant application are enabled. In fact, Dr Steuer states (see page 1 of the final report) "reintroduction of an aerobic atmosphere during an anaerobic cell culture phase resulted in the **isolation** of bacteria, specifically *Bacillus lichenformis*". Additionally, the results presented by Dr Steuer were obtained using a single cell strain (RT-HMCV) and resulting in the **isolation** of a single known bacterial strain.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-14, 19-23 and 30-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended the claims 30 and 31 to recite "free of any over microbiological contamination...". This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. Therefore this limitation is new matter.

Applicant has amended the claims 30 and 31 to recite "under sterile culturing conditions...". This phrase does not appear in the specification, or original claims as filed.

Applicant does not point out specific basis for this limitation in the application, and none is apparent. Therefore this limitation is new matter.

Applicant has amended the claim 31 to recite "one gene evolved from the genome of said eukaryotic cell". This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. Therefore this limitation is new matter.

Applicant has amended the claim 30 to recite "identifiable as a bacteria and contains a eukaryotic and/or viral gene". This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. Therefore this limitation is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-14, 19-23 and 30-31 rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 4-14, 19-23 and 30-31 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in the reply filed 11-17-2003. In that paper, applicant has stated that the instant claims are drawn to "methods for **producing a bacterium** that contains a eukaryotic and/or viral gene which comprises culturing virally-infected eukaryotic cells under low-oxygen conditions and this statement indicates that the invention is different from what is defined in the claim(s) because said statement requires that the genome of the "produced" bacteria is prokaryotic in nature

suggesting that the claimed method induces a "de-evolution" of the eukaryotic cell. The instant claims are drawn to cells identifiable as a bacteria and containing a eukaryotic and/or viral gene. Said claims are drawn to any cell that has the phenotype of a prokaryote regardless of its genomic organization (i.e. eukaryotic vs. prokaryotic genome) not a bacteria and containing a eukaryotic and/or viral gene.

Claims 4-14-, 19-23 and 30-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30 and 31 are rendered vague and indefinite by the use of the phrase "under sterile conditions". It is unclear how one can culture cells "under sterile conditions" when, by definition; "sterile conditions" require the lack of living matter.

Claim 31 is rendered vague and indefinite by the use of the phrase "gene evolved from the genome of said eukaryotic cell". It is unclear what is meant by said phrase, as it is not explicitly defined in the specification. Consequently, it is impossible to determine the metes and bounds of the claimed invention.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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ROBERT ZEMAN
PATENT EXAMINER

May 31, 2006